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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,644

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

09/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No. 10/528,644	Applicant(s) SUNG ET AL.	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-17,20-35 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) 30,35 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17,20-29,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed October 16, 2009 in response to the Office Action of June 17, 2009 is acknowledged and has been entered. Sequence listing filed March 31, 2010 is acknowledged.

Claims 7, 9, 11, 13, 24, 26, 28, 33, 35 and 38-40 have been amended. Claims 30-35 and 40 are withdrawn. Claims 1, 2, 5-17, 20-29, 38 and 39 are under examination.

Claim Rejections - 35 USC § 112

Rejection of Claims 7-15, 22-29, 38 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

Rejection of Claims 1, 2, 5, 6, 16, 17, 20, 21, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (US Patent 5,731,172) in alternative over Tang et al. (US 2004/0166488 A1) in view of Lee et al. (Virology, 2001, Vol. 279, p. 271-279) **is withdrawn** in view of Applicant's filing the English translation of the priority documents.

New Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 5, 6, 16, 17, 20, 21, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (US Patent 5,731,172), in view of Encke (Journal of Immunology 1998, Vol. 161, p. 4917-4923) Choo (PNAS, 1994, Vol. 91, p. 1294-1298) and Large (Journal of Immunology, 1999, Vol. 162, p. 931-938).

Saito et al. teaches a recombinant adenovirus vaccine comprising plasmids expressing the HCV genes (see Example 2). Although Saito et al. does not specifically disclose which HCV genes are expressed by the recombinant adenovirus, because Saito et al. broadly speaks about the whole HCV genome, it is expected that all HCV genes, including E1, E2, NS3, NS4, and NS5 are present in Saito's recombinant adenoviral vaccine.

Encke teaches DNA vaccine composition comprising plasmids encoding NS3, NS4, and NS5 genes of HCV (see Materials and Methods). Choo teaches vaccine composition comprising plasmids encoding E1 and E2 genes of HCV (see Materials and Methods). With regard to the limitations drawn to the size of the plasmids, the size of the particular genes comprised within the vaccine disclosed by Encke et al. is expected to range from 2 to 4 kb, because the HCV genes of the current invention and HCV genes disclosed by Encke. have identical structure. Although some variations may exist in different strains of the HCV virus with respect to the particular nucleic acids and certain positions, the length and thus the size of the genes remain the same.

Neither Saito, Encke, nor Choo teach 35-40 amino acids eliminated from the N-terminal region of the core protein.

Large teaches that the N-terminal half of the HCV core protein has immunosuppressive properties (see the entire document, particularly abstract and Results).

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It would have been *prima facie* obvious to provide Saito's composition comprising Encke plasmids encoding NS3, NS4, and NS5 genes of HCV and Choo plasmids encoding E1 and E2 genes of HCV because Saito suggests using adenovirus to express HCV proteins.

It would have been *prima facie* obvious to eliminate the 35-40 amino acids of the N-terminal region of the HCV core protein, because Large teaches that that the N-terminal HCV core protein has immunosuppressive properties (see the entire document, particularly abstract and Results).

One would have been motivated to remove 35-40 amino acids of the N-terminal region of the HCV core protein because in order to avoid immunosuppression which could lower the immune response to the immunogenic construct.

Thus the present invention would have been *prima facie* obvious to the skilled artisan at the time the invention was made.

Conclusion

No claim is allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Examiner, Art Unit 1648